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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,364	07/31/2003	James Wagner	MIY-P01-032	2195
28120 7590 06/19/2007 FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER GILBERT, SAMUEL G	
			ART UNIT 3735	PAPER NUMBER
			MAIL DATE 06/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/631,364

Applicant(s)

WAGNER ET AL.

Examiner

Samuel G. Gilbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :portion of the ids from 12/24/2003(6 pages).

DETAILED ACTION

Information Disclosure Statement

References B52 and B63, C1-C25, C27-C33, C35-C60 and C62-C75 have been considered. References C26, C34 and C61 have not been considered because no dates have been provided.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7, 9-11 and 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Gellman et al (6,042,534)

Claim 1 - element 10- is a sling, an absorbable coating is considered a casing, column 8 lines 3-13. When the coating is applied to the sling, the sling fills a volume the examiner is considering a lumen in the coating. The examiner is taking the coating to be considered a sleeve.

Claim 7 - gelatin is taught for the coating, column 8 line 15.

Claim 9 - polyvinyl alcohol is taught in column 8 line 16.

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Claim 10 - polyglycolic acid is taught in column 8 line 14.

Claim 11 - polylactic acid is taught in column 8 lines 14 and 15.

Claim 13 - the examiner is taking the coating to be inherently lubricious.

Claim 14 - the sling is capable of being placed as claimed.

Claims 15 and 16 - the claims do not set forth any specific structure to perform the recited functional language therefore the examiner believes the coatings as taught by Gellman et al. will inherently perform as claimed.

Claims 17 and 18 - Gellman et al sets forth a method of providing the sling and casing and positioning it within the periurethral tissues.

Claims 1 and 13-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Chu et al (2004/0225181).

Claim 1 - element 16 is a sling and element -18- is a bioabsorbable sleeve, paragraphs [0065] and [0075]. The examiner is taking the sleeve -18- as a casing. The sleeve contains a lumen. The sleeve -18- is considered a coating.

Claim 13 - the examiner is taking the sleeve -18- to be inherently lubricious.

Claim 14 - the sling is capable of being implanted as claimed.

Claims 15 and 16 - the claims do not set forth any specific structure to perform the recited functional language therefore the examiner believes the coatings as taught by Chu et al. will inherently perform as claimed.

Claims 17 and 18 - Chu et al sets forth a method of providing the sling and casing and positioning it within the periurethral tissues.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6, 8, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gellman et al (6,042,534) in view of Shekalim et al (6,971,813) and Ochoa et al (5,935,172). Gellman et al teaches a device as claimed but does not teach each particular element of the casing as claimed. Gellman et al teaches a coating(casing) to deliver therapeutic compounds to the body. Shekalim et al teaches a plurality of such therapeutic coatings. Applicant's attention is invited to column 2 lines 7 through column 5 line 31. Ochoa et al teaches polydioxanone among other absorbent material. In the absence of showing any criticality in the exact material selected for the bioabsorbable material the selection of any particular material would have been an obvious design expedient to one of ordinary skill in the medical arts.

Claims 4-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al (2004/0225181) in view of Shekalim et al (6,971,813) and Ochoa et al (5,935,172). Chu et al teaches a device as claimed but does not teach each particular element of the casing as claimed. Coating (casing) is known to deliver therapeutic compounds to the body. Shekalim et al teaches a plurality of such therapeutic coatings. Applicant's attention is invited to column 2 lines 7 through column 5 line 31. Ochoa et al teaches

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polydioxanone among other absorbent material. In the absence of showing any criticality in the exact material selected for the bioabsorbable material the selection of any particular material would have been an obvious design expedient to one of ordinary skill in the medical arts.

Response to Arguments

Applicant's arguments filed 3/19/2007 have been fully considered but they are not persuasive.

The applicant argues that the bioabsorbable sleeve is not found in 60/465,722 to Chu and therefore Chu is only entitled to the filing date for that subject matter. It is the examiners position that the provisional application 60/465,722 includes teachings of a bioabsorbable coating which may be found throughout the application and at least on page 859, where absorbable coatings are disclosed. Therefore, the examiner believes Chu is entitled to the filing date of the provisional application for the claimed subject matter.

The arguments regarding Shekalim et al, teaches a liquid or semiliquid for the coating. The examiner would like to point out that Shekalim et al also teaches the use of films. Therefore as set forth above, the combination as set forth is considered to have a lumen as set forth above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

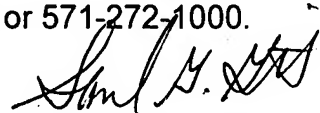
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Samuel G. Gilbert
Primary Examiner
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